REMARKS

This responds to the Office Action mailed on November 14, 2007.

Claims 59-78, 81-106 and 107 are now pending in this application. However, claims 59-73, 77, 85-106 are withdrawn from consideration. Accordingly, claims 74-76, 78, 81-84 and 107 are now under examination.

Claims 74 and 107 are amended. Claim 74 now contains the term "blood-borne." Support for monitoring blood-borne substances can be found throughout the specification, for example, at page 17, lines 10-13. The language of claim 107 has been clarified by recitation that that the mammalian subject is pretreated with platelet derived growth factor at the site of implantation. Support for this subject matter is present in the application as filed, for example, in Example III.

Applicant submits that no new matter has been added to the application.

Interview Summary

Applicants wish to thank Examiner Mallari for extending the courtesy of a telephone interview to Applicants' representative, Robin A. Chadwick, on February 8, 2008.

Applicants' representative inquired about the need for a drawing for the subject matter of claim 107. The Examiner stated that if the recited platelet derived growth factor is part of the biosensor then a drawing is needed. However, if the platelet derived growth factor is not part of the biosensor, then no drawing is required. Applicants have amended claim 107 to clarify the subject matter therein, by reciting that the mammalian subject is pretreated with platelet derived growth factor at the site of implantation. Support for this subject matter is present in the application as filed, for example, in Example III.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in his next communication so that Applicants can amend or supplement the interview summary.

Drawings

The Examiner has objected to the drawings as allegedly failing to show the subject matter of claim 107. As indicated above, the Examiner explained in a telephone interview that if the recited platelet derived growth factor is part of the biosensor then a drawing is needed. However, if the platelet derived growth factor is not part of the biosensor, then no drawing is required. Applicants have amended claim 107 to clarify the subject matter therein, by reciting that the mammalian subject is pretreated with platelet derived growth factor at the site of implantation (see Example III).

Applicant submits that no drawing is needed because the platelet derived growth factor is not part of the biosensor. Withdrawal of this objection to the drawings is respectfully requested.

§112 Rejection of the Claims

Claim 107 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description.

The language of claim 107 has been clarified by recitation that the mammalian subject is pretreated with platelet derived growth factor at the site of implantation. Support for this subject matter is present in the application as filed, for example, in Example III.

Withdrawal of this rejection of claim 107 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

§102 Rejection of the Claims

The Examiner has made two rejections under section 102 that are separately discussed below.

Claim 74 is directed to an implantable physiological or pathophysiological biosensor comprising: in vitro or ex vivo modified stem cells coupled to an electrical interface and adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject, wherein the in vitro or ex vivo modified stem cells can monitor a blood-borne chemical, physiological or pathophysiological variable associated with the physiological or

pathophysiological function of the subject and can produce a coagulation factor, serotonin, a growth factor, a hormone, or a receptor.

Palti

Claims 74, 76-78, and 80-83 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Palti (U.S. Patent No 5,368,028). According to the Examiner, mention of any cell type and a disclosure of Beta cells by Palti is a disclosure of the stem cells of the claimed invention. As proof, the Examiner cites Palti at col. 9, lines 16-31; at col. 6, lines 14-19; col. 11, lines 4-25; at col. 6, line 66 to col. 7, line 9; at col. 11, line 44 to col. 12, line 26.

Applicant submits that this rejection cannot be maintained when Palti clearly fails to disclose the following elements of the invention: in vitro or ex vivo modified stem cells. Palti fails utterly to mention "stem cells" and teaches nothing about genetically modified cells.

The Examiner alleges that language relating to "in vitro or ex vivo modified stem cells" makes claim 74 into a product-by-process claim. Applicant submits that a stem cell is a physical entity – a specific cell type readily recognized and isolated by one of skill in the art – not a process step. Moreover, a modified cell (e.g., capable of producing a coagulation factor, serotonin, a growth factor, or a receptor) is also a physical entity, not a process step. Accordingly, Applicants respectfully request that the Examiner consider the actual structure of the claimed subject matter rather than some structure that might hypothetically evolve from Applicants' claimed subject matter.

Applicants further submit that the cited text in Palti discloses nothing relevant to the missing elements. Palti at col. 9, lines 16-31, discloses that any cell type (e.g., Beta cells) with detectable electrical activity can be used as sensors. Palti fails to disclose use of stem cells.

Palti at col. 6, lines 14-19, discloses collecting means for electrical signals.

Palti at col. 11, lines 4-25, discloses ways to detect electrical activity (electrodes, conducting bars, amplifiers, etc.).

Palti at col. 6, line 66 to col. 7, line 9, discloses that a chemical signal emitted by the chemo-sensor cells can be detected by photometric means or as an electrical or optical signal through the skin.

Palti at col. 11, line 44 to col. 12, line 26 further discloses ways to detect electrical activity of implanted cells.

Nowhere does Palti disclose that the cells should be stem cells. Nowhere does Palti disclose that the cells should be genetically modified. Nowhere does Palti disclose that cells producing a coagulation factor, serotonin, a growth factor, or a receptor should be employed.

Applicant respectfully requests withdrawal of this rejection under section 102.

Field

Claims 74-76 and 80-84 were rejected under 35 U.S.C. § 102(e) for anticipation by Field (U.S. Patent Application No 2003/0211088).

Field is limited to cardiomyocyte-enriched cellular populations that may be used to engraft mammalian myocardial tissue, for example, to provide biological pacemakers. These cells are implanted into the heart tissue of a mammal and respond to localized electrical signals from the heart.

The Examiner has criticized Applicants' emphasis upon implantation of the biosensor at a site distant from a natural site for a physiological or pathophysiological function of the subject. However, the requirement for such distant implantation means that the biosensor has different features than Field's cardiomyocyte-enriched cellular populations.

In particular, Field fails to disclose cells that monitor to blood-borne a blood-borne chemical, physiological or pathophysiological variable associated with the physiological or pathophysiological function of the subject. Instead, Field is limited to cells that are integrated into the natural site where their function is normally performed – i.e., in the heart to replace defective pacemaker functions. Field explicitly teaches that these pacemaker cells should be directly coupled to cardiac ganglia so that they can optimally perform their function. See. Field at paragraphs 33, 35, 40-42 and 58-61. Thus, Field's cells do not monitor a blood-borne variable and respond to that blood-borne variable. Instead, Field's cells purportedly respond to localized electrical activity in the heart.

Moreover, Field also fails to disclose administration of the biosensor to a mammalian subject pretreated with platelet derived growth factor at the site of implantation.

Accordingly, Field fails to teach several elements of the claimed invention. Applicant respectfully requests withdrawal of this rejection under section 102.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (516) 795-6820 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date May 14, 2008 By /Robin A. Chadwick/

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CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelop addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 14th day of May 2008.

Name: Dawn M Pate Signature: Dawn M. Pate